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09/489,310 01/21/00 STEPHENSON

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EXAMINER

ROSE, S

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

06/04/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/489310

Applicant(s)

STORINSON L

Examiner

STEP RABO

Group Art Unit

1614

—The MAILING DATE of this communication appears in the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

☒ Responsive to communication(s) filed on 4/27/2001

☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 165 74/5 17222 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 165 74/5 17222 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Claims 6 and 16 are canceled and claims 21 and 22 newly presented and the balance of the claims amended to have the beverage substantially free of calcium and fluoride.

A telephone interview Friday May 25, 2001 between the undersigned USPTO Examiner and applicants' counsel, Kelly McDaw-Dunham, clarified the page 8 election, with traverse, of one ultimate disclosed species of (B) beverages containing fruit juice and © carbohydrate sweeteners, since both are generic to plural species. All fruit juice species and all carbohydrate sweeteners are considered to be obvious variants of each other, and, accordingly, are not to be regarded as patentably distinct species.

The election, without traverse, is of:

(A) sodium hexametaphosphate,  $n=21$ ; (as in Examples 3 and 4);

(B) beverages containing fruit juice; (as in Examples 3 and 4);

© carbohydrate sweeteners, as high fructose corn syrup (Example 3) , or sugar (Example 4);

(D) substantially free of calcium and fluoride, (both known to reduce tooth erosion in beverages) as required by the claims as presently amended.

The Examiner regards claim-encompassed polyphosphates and elected sodium hexametaphosphate ( $n=21$ ) as well-known commercially available source compounds to yield phosphate ion in water, and the tooth erosion benefit of the sodium phosphate salt monosodium dihydrogen phosphate, "MDP",  $\text{NaH}_2\text{PO}_4$  discovered by McDonald et al and Muhler to reduce

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tooth erosion, to be due to the expected release of phosphate ion upon aqueous dissolution of the phosphate salt.

Whether or not the selection of sodium polyphosphate would be immediately envisioned for the same tooth erosion benefit, or whether or not one skilled in the art would have motivation to substitute sodium polyphosphates for the tooth erosion benefitting monosodium dihydrogen phosphate, based on expert knowledge that both are well known sources of phosphate ion requires a Rule 132 Declaration of an expert (i.e. by applicants or colleagues). Counsel's remarks are not considered herein to be an expert's opinion.

The undersigned USPTO Examiner has referred to management officials, sector mentors, the very interesting legal agreement for the "KITS" (information on dental erosion) on In re Haller, 73 USPQ 403, based upon In re Miller, 164 USPQ 46, and In re Gerlick, 217 USPQ 401, and has been advised, in the interim, that the policy of this sector, is to distinguish both cases as reacting functional structural elements claimed, more that "information", etc. "KITS" of old compositions whose patentable novelty depends on printed information on a new use are involved.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1 to 5, 7 to 15, 17 to 22 rejected under 35 U.S.C. 102(a)(b)(e) as being anticipated by each of condensed phosphate or polyphosphate salt supplemented low pH beverages of the U.S. patents cited on the PTO-892, namely, the commonly assigned Proctor & Gamble patents to:

Calderas (sodium hexametaphosphate, same as herein), Smith et al., Montezinos (I-II), Ekanayake et al. (same), McKenna et al., Tung et al. , Cirigliano et al. (I-II), Sokolik et al. , and Zablocki et al. each describing encompassed species of beverages having a pH less than about 5, containing sodium hexametaphosphate, (same as herein), or other encompassed species of sodium or potassium, condensed phosphate or polyphosphate salts, Calderas, for example employing 900 to 3000 parts per million polyphosphate with sodium hexametaphosphate, same as applicant herein in Examples 1-4), as the encompassed polyphosphate, in a non-carbonated beverage having a pH of between 2.5 and 4.5, as see column 4 lines 7-32 in fruit juices at column 7 lines 39-68, and tea at column 8 lines 12-28, with encompassed species of sweeteners at column 8 lines 30-68, also avoiding calcium as well as iron and magnesium fortification since these polyvalent cations combine to and inactivate the polyphosphate component of the non-carbonated beverages, as see column 9 lines 27-30.

Smith et al. (Proctor & Gamble), similar to Calderas (Proctor & Gamble), include

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300 ppm to 3000 ppm of an encompassed polyphosphate having an average chain length of about 17 to about 60, an encompassed species of a non-carbonated beverage having a pH of between 2.5 and 4.5.

The prior art polyphosphate supplemented acid beverages meet the step of the method by drinking them, and do not become patentable "KITS" by being labeled with information to the effect that since polyphosphates may prevent tooth caries, as see Shibata et al. (1982), that they may reduce their tooth erosion potential of the acid low pH beverages, a property described by Lussi et al., (1995).

Applicant's attention is directed to legal decisions, binding on USPTO patent examiners, on a vital issue of "new use" of known compositions.

Ex parte Novitski, 26 USPQ 2d 1389 (January 22, 1993), is a decision of the USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculant, heretofore employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculant would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated. Nevertheless, the step of inoculating plants with the same inoculant necessarily and inherently protects them against nematodes.

Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir.-1999), holds that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not precluding a finding of anticipation. Whether or not an

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element is inherent in the prior art, is a fact question. Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new to the discoverer. The fact that the prior art taught away from the claim is, in fact, only “a showing that the prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency. The “KITS” are not patentably distinct by virtue of (B) information , as noted above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 to 5, 7 to 15, 17 to 32 rejected under 35 U.S.C. 103(a) as being unpatentable over the foregoing sodium hexametaphosphate added acidic pH fruit juice beverages described by each

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of the foregoing: Calderas, Smith et al, Motezinos (I-II), Ekanayake et al, McKenna et al, Tung et al, Ciriglione et al (I-II), Soklik et al, and Zablocki et al (details as noted above) none of which describe the reduction of tooth erosion benefit imparted to the acidic pH fruit juice benefit by virtue of the sodium hexametaphosphate, taken in further view of Shibata et al (1982) or McGaughey et al (1977) and each of Muhler (1970) (as abstracted) and McDonald et al. (1973) (Details as noted above), each anticipating the addition of a sodium or potassium phosphate salts to such a low pH acid beverage to reduce their tooth eroding potassium polyphosphates or condensed phosphate salts as well as the selection of encompassed low pH acid beverage species, to practice this would be prima facie obvious as an apt source for phosphate ion, if not immediately envisioned, In re Schaumann et al ., 197 USPQ 5. The feature of kit claims 11-20 of including information that the use of the beverage provides treatment against dental erosion is not patentable thereover, (In re Haller, 73 USPQ 403, CCPA-1947) since it is predicated on printed matter on the otherwise old beverage or its package.

Applicant has presented twenty (20) claims, claims 1 to 5, 7 to 10 and 21 drawn to the step of drinking a known beverage, to treat dental erosion by its oral administration, and claims 11 to 15 and 17 to 20 and 22 to "KITS" (no more than label information), of such admittedly known species of acidic beverages having a pH of less than 5, which admittedly are considered to directly erode dental enamel, admittedly, according to Lussi et al. (1995), Caries Research Volume 29 pages 349-354; it being admitted prior art that the encompassed species of acidic low pH dental eroding beverages include : fruit juice, as elected, carbonated cola and other soft drinks; as well as



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tea; milk and milk based beverages; (containing fluoride and calcium, respectively), it being admitted prior art that fluoride and/or calcium can expectedly lessen dental erosion, the improvement to such dental eroding ingestible acid low pH beverages free of calcium and fluoride being that the beverage contains sodium or potassium polyphosphate salts. This is "new use" of a known beverage, another reason to drink it. Is this patentable?

The novelty of kit claims 11 to 15, 17 to 20 and 22, over inadvertently overlooked not admitted above note cited and applied prior art acidic beverages containing the sodium or potassium species of encompassed polyphosphates (included described or taught for reasons other than to treat dental erosion) (cited as known on the PTO-892 attached), (clearly meeting Part (a) of claim 1), is found in Part (b) of "KIT", "INFORMATION THAT THE USE OF THE BEVERAGE COMPOSITION PROVIDING TREATMENT AGAINST DENTAL EROSION".

The CCPA in 1947 in In re Haller, 73 USPQ 403, held that novelty cannot be predicated on printed instructions (or on a label to reconstitute or to dilute a known composition with water to use it as an insecticidal spray). This Court case never overturned is binding as a precedent and Federal Circuit precedents are binding on USPTO examiners. The Miller and Gulack decisions can be distinguished on their facts, they involve functional elements claimed in Miller, a ratio indicating legend and volumetric indicia on a measuring receptacle in Gulack the printed material was novel and non-obvious both cases are prior to the recent Atlas case.

A review if the applicant cited admitted prior art cited on the PTO-1449 IDS includes:

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Lussi et al. (1995) (as noted above) identifying the species of low pH tooth erosive acid beverages encompassed by these claims to include orange juice and other citrus and fruit juices, apple juice, Sprite, Coca cola, Lemon Lime and other carbonated soft drinks, Sweppes, sports drinks, wine and beer, to which fluoride had been added to minimize (but not totally prevent) tooth erosion.

Ruessner et al (1975), describe and anticipate the addition, to encompass species of beverages, namely encompassed pH range canned and frozen orange juice, and carbonated lemon lime beverages, of encompassed percentages of phosphates, namely (page 366, column 1, Table I), 0.15% sodium trimetaphosphate; 0.21% monosodium orthophosphate ( $\text{NaH}_2\text{PO}_4$ ); with or without 0.08% monofluorophosphate, or 0.15% calcium chloride, the levels of the phosphate compound selected to yield 0.5 mg of phosphorus per ml, and 0.5 mg per ml of calcium. A control group had no calcium or polyphosphates in encompassed concentrations, with and without sucrose and/or glucose, as providing anti-carries activity, as tested at 2% phosphate level and high sugar diet in hamsters in the absence of fluoride, in Shibata et al.

Examiner cited Muhler (1970) South Africa 6904743, and McDonald et al. (1973), both cited on the PTO-892 teach and describe the feature of adding a sodium phosphate salt-monosodium dyhydrogen phosphate to acid pH beverages to reduce tooth erosion, same as herein. The feature of selecting polyphosphate as phosphate sources would be prima facie obvious, if not in fact "immediately envisioned" species under In re Schaumann et al ., 197 USPQ

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Shibata et al. (1982), and McGaughey et al. (1977), (both cited by applicant) each motivates the inclusion in the diet of encompassed species of these condensed phosphates of polyphosphates.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday-Thursday from 7:30 am to 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shep Rose  
Senior Primary Examiner  
Art unit 1614

SKR:mv  
May 30, 2001

**SHEP K. ROSE  
PRIMARY EXAMINER  
GROUP 1200**